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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF DARREN R. HURST, M.D., AND SUPPORTING MEMORANDUM OF LAW

(ASSIGNED TO THE HONORABLE DAVID G. CAMPBELL)

(ORAL ARGUMENT REQUESTED)

INTRODUCTION

Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny, Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), respectfully move to exclude certain expert opinion testimony offered by Darren M. Hurst, M.D. ("Dr. Hurst"), an

interventional radiologist. Bard's Motion is supported by the following Memorandum of Points and Authorities and any oral argument the Court may entertain.

MEMORANDUM OF POINTS AND AUTHORITIES

Bard seeks to exclude the following opinions of Dr. Hurst:

1. Bard filters had higher complication rates than other manufacturers' filters and an "unacceptable" rate of caudal migration.
2. Bard ignored safety signals with its filters, and elected not to perform additional studies to evaluate durability, safety, and efficacy, all while falsely representing superior safety, quality, and performance.
3. Bard failed to communicate to doctors that the Meridian® should be used instead of the Eclipse® and G2X® in patients like Ms. Mulkey, Ms. Jones, and Ms. Hyde.

Bard seeks to exclude these opinions on the grounds that Dr. Hurst is either not qualified to give these opinions, has failed to provide reliable, scientific methodology to support these opinions, and relies solely upon limited documents selected by plaintiffs' counsel to reach otherwise unsubstantiated conclusions. These opinions are unreliable and will not assist the trier-of-fact in determining the issues in this case.

ARGUMENT AND CITATION OF AUTHORITY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE DR. HURST

For an expert's opinion to be admissible under Federal Rule of Evidence 702, the Court must find that "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Rule 702 incorporates principles established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), in which the Supreme Court charged trial courts with a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." (*Id.* at 589.) Ultimately, the objective of *Daubert* is "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes

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the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The proponent of expert testimony must demonstrate admissibility by a preponderance of proof. *Daubert,* 509 U.S. at 592 n. 10; *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). And "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under the above *Daubert* standard, the opinions discussed in this Motion are unreliable.

A fundamental requirement of Rule 702 is that the proposed scientific/technical testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." The Ninth Circuit has found that "[f]ederal judges *must* . . . *exclude* proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to [the] issue in dispute in the case, and that it will not mislead the jury." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) (emphasis added).

The opinions of Dr. Hurst identified above will not assist the trier-of-fact and should be excluded. *See e.g., U.S. v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) (also noting that expert opinion is not helpful to the trier of fact "when it offers nothing more than what lawyers for the parties can argue in closing arguments"); *In re: Trasylol Prods.. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (excluding testimony concerning regulatory history, FDA correspondence, and internal company documents, noting that the issues should be presented to the jury directly, not through an expert who "regurgitates them and reaches conclusory opinions . . . and invades the province of the jury."); *In re: Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007) (excluding testimony as "lay matters" and "conclusory statements about questions of fact masquerading behind a veneer of technical language" where plaintiffs proffered an expert to opine that Bayer ignored its toxicologists' concerns about Baycol's steep dose-response curve as it concerned Baycol's safety profile); *In re: Rezulin Prods. Liab. Litig.*, 309 F.

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Supp. 2d 531, 555 (S.D.N.Y. 2004) (excluding expert testimony concerning the alleged downplaying of hepatotoxic effects of Rezulin in the published literature based on internal documents, memos, and e-mails, finding that the issues constituted "lay matters" and would amount to arguing from the witness stand).

1. Dr. Hurst Is Not Qualified to Opine That Bard Failed to Comply with Some Duty to Notify Doctors and Patients of Allegedly Higher Complication Rates.

In his Rule 26 Report for each of the five bellwether plaintiffs, Dr. Hurst states "Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2, and Eclipse filters, in comparison to the original predicate device, the Simon® Nitinol Filter, and competitor filters."[1] (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(i),* at 9.) Dr. Hurst also states that, based on adverse event reports/sales data, medical literature and internal Bard documents, the G2 filter had an "unacceptable risk of caudal migration." (*Id.* at *Opinion 4(d)(ii),* at 9-10.)

A. Dr. Hurst should not be permitted to opine that Bard filters had higher complication rates than other manufacturers' filters and an "unacceptable" rate of caudal migration.

Dr. Hurst is neither qualified to provide an opinion on what the complication rates are in Bard filters, nor is he qualified to say that they have "higher complication rates" as compared to any other IVC filters. He has not provided any scientific methodology which supports the reliability of that opinion. The two bases Dr. Hurst states for his opinion that there are "higher rates" in Bard filters are: (1) "I feel like . . . the risk of complications from the [Bard] filters is much higher in general in comparison to both permanent and other retrievable filters," (Ex. B, Hurst Dep. Tr., 255:19-256:9, August 7, 2017) and (2) his review of an article which purports to have gathered information on filter complications reported in other published studies of IVC filters. (Ex. C, Steven E. Deso, M.D., *et al., Evidence-Based Evaluation of Inferior Vena Cava Filter Complications*

[1] Bard attaches and cites Dr. Hurst's Rule 26 Report from the Debra Mulkey case herein, by way of example.

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Based on Filter Type, Semin. Intervent. Radiol. 2016; 33:93-100.) Dr. Hurst describes *Deso* as "a meta-analysis of all the filters . . . a combination of basically all of the literature up-to-date on IVC filters at that time. So there's multiple articles that would support that." (Ex. D, Hurst Dep. Tr., 33:17-34:15, July 21, 2017.) These bases for Dr. Hurst's opinions on rates are insufficient for several reasons.

Dr. Hurst is a medical doctor with a specialty in vascular and interventional radiology. (*Id.* at 7:13-14). There is no evidence in the record indicating that Dr. Hurst is a biostatistician or an epidemiologist. Consequently, what he "feels" about rates in Bard filters does not spring from any formal expertise in determining the rates of adverse events. With respect to his reliance on the *Deso* article (*"Deso"*) as proof of this opinion, Dr. Hurst is not qualified, since he has no expertise in statistics or epidemiology, to give an expert opinion that the events reported in *Deso* are complete, accurate, or provide reliable rate information for Bard filters. Even if he were qualified to make such an analysis, Dr. Hurst has done no work to verify the information reported in *Deso*, to analyze what information may be missing, whether the information utilized was subject to biases making the information unreliable, and the extent to which one can or cannot draw the conclusions he reached from a statistical or epidemiological standpoint. (Ex. B, Hurst Dep. Tr., 267:14-269:12, August 7, 2017.)

When asked if there is any published study comparing Bard retrievable IVC filter rates head to head with other IVC filters, Dr. Hurst conceded that no such comparative study exists: "No one has done, though, a comprehensive study. That study is ongoing, it's called the PRESERVE trial." (Ex. D, Hurst Dep. Tr., 33:17-34:15, July 21, 2017.) Dr. Hurst adds "the reason the PRESERVE trial is ongoing right now and it was -- the reason that it was so important is that I think there was a recognition that the data for filters in general was lacking." (*Id.* 41:17–25)

Dr. Hurst also opines that the G2 filter had an "unacceptable risk of caudal migration," (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(i)*, at 9-10.) However, he conceded that "[t]he mere fact that a complication occurs

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doesn't mean that the risks outweighs the benefits? No, no. I mean, you have to -- you can't -- I guess you have to qualify that statement by saying you need to know the degree of risk of the complication in order to weigh it against the benefits." (Ex. D, Hurst Dep. Tr., 31:23-32:9, July 21, 2017.) However, Dr. Hurst does not provide record evidence about what the rate of caudal migration is for Bard filters, and he does not state his bases for concluding that the rate is "unacceptable." (*Id*. at 102:22-103:8) Dr. Hurst testified that his analysis to form this opinion amounted to his review and interpretation of a Bard internal document that discusses caudal migration. (Ex. B, Hurst Dep. Tr., 253:20-256:9, August 7, 2017.) He performed no independent analysis to determine the rate of caudal migration in Bard filters compared to the rate in competitive filters. (Ex. D, Hurst Dep. Tr., 60:11-61:7, July 21, 2017.) Other than *Deso*, he points to no study that shows the rates of caudal migration, in Bard filters, how that compares with caudal migration in other filters, or how that makes the frequency of this event "unacceptable." And he does not point to the FDA or any other agency or medical organization which has found this frequency to be "unacceptable". In sum, Dr. Hurst is unqualified to proffer his opinions regarding what the rates of caudal migration are in Bard filters, and he has failed to employ any scientific methodology to determine what those rates are, whether they are "unacceptable," and to whom.

Courts have limited the scope of an expert's opinions where they venture into areas outside the scope of their qualifications. *See e.g. Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the 'reasonable confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science, and that therefore the physician was not qualified to offer such opinions); *In re Silicone Breast Implants Litig.*, 318 F.Supp.2d 879, 902 (C.D.Cal. 2004) (excluding opinions about the defendant's failure to conduct tests proffered by the plaintiff's expert, who had worked in quality control for a pharmaceutical company, published papers about medical devices, and holds patents on medical devices, on the

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grounds that such experience is insufficient foundational knowledge for offering opinions on testing); *Kruger v. Johnson & Johnson Professional, Inc.*, 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001) (finding that a metallurgist was unqualified to offer design opinions regarding bone screws where he had no experience in the design of medical implants or any other medical devices). Courts have similarly limited the scope of an expert's opinions where that expert failed to use scientific methodology to show the reliability of his assertions. Indeed, "'[t]he reliability prong mandates that expert opinion be grounded in the methods and procedures of science and . . . be more than unsupported speculation or subjective belief.'" *Harris v. Spine*, 39 F. Supp. 3d 846, 850 (S.D. Miss. 2014) (quoting *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012)) (ellipsis in original). The proponent of expert testimony must demonstrate admissibility by a preponderance of proof. *Daubert, 509 U.S.* at 592 n. 10. "'The expert's assurances that he has utilized generally accepted scientific methodology is insufficient.'" *King v. Synthes (U.S.A.)*, 532 F. Supp. 2d 828, 832 (S.D. Miss. 2006) (quoting *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998)).

Like the many courts that have excluded or limited the scope of opinions outside an expert's particular area of qualifications, and for lack of reliability, the Court should exclude Dr. Hurst's testimony about rates because he has no formal education, experience, training, or foundational knowledge to determine from any source what the "rates" are, admits there are no studies which provide comparative rates between IVC filters on the market, and he has done nothing to verify the reported information in *Deso* which he relies so heavily upon as the basis for these opinions.

2. Dr. Hurst is Not Qualified to Say Bard Ignored Safety Signals With Its Filters, and Elected Not to Perform Additional Studies to Evaluate Durability, Safety, and Efficacy, All While Falsely Representing Superior Safety, Quality, and Performance.

In a series of opinions that are closely related, Dr. Hurst claims that: (1) Bard ignored early safety signals from adverse event reports, sales data, medical literature, its own testing, and internal risk analysis with the Recovery, G2, and Eclipse filters (Ex. A,

Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(ii)*, at 9-10); (2) Bard chose not to conduct additional studies to further evaluate safety, durability, and efficacy (*Id*. at *Opinion 4(d)(vi)*, at 11)[2]; and (3) Bard falsely represented improvements in newer generation filters through marketing materials. (*Id*. at *Opinion 4(d)(v)*, at 11.)[3]

Dr. Hurst is not qualified to offer opinions about the design, testing, and marketing of Bard filters, or any of Bard's internal decisions or follow-up diligence related to its filters. Again, he is not trained as a biomedical engineer, or in the design, manufacture, and labelling of medical devices, (Ex. E, Hurst Dep. Tr., 21:18-22:17, August 19, 2016.), and he admits that he is not an FDA regulatory expert. (Ex. D, Hurst Dep. Tr., 42:4-16, 69:23-70:19, July 21, 2017.) Once again, the case law cited in Section 1, *supra*, provides examples where courts have excluded or limited the scope of opinions where the expert ventures outside of his or her particular expertise.

In addition, Dr. Hurst also fails to offer any methodology to support these opinions. His foundation comes almost exclusively from twenty-four (24) Bard emails and documents, and select depositions from this litigation, provided to him by plaintiffs' counsel. (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Appendix*, at 15-17.);

[2] Dr. Hurst also comments in *Opinion 4(d)(vi)*, that Bard conducted a "decade long open experiment with Bard retrievable filters" instead of "perform[ing] studies to further evaluate the safety, efficacy, and durability of their filters." Bard not only contends that this testimony should be excluded for the reasons stated in this Section (i.e. lack of qualification to offer these opinions and insufficient methodology and factual basis for these opinions), but also because this statement is unduly prejudicial to Bard under Federal Rule of Evidence 403.

[3] Dr. Hurst also goes beyond the realm of his experience in *Opinion 4(d)(v)*, when stating that Bard falsely represented the qualities of its newer generation filters through its marketing materials. Though Dr. Hurst has reviewed some Bard marketing materials and had personal experience with Mike Kirksey, the Bard sales representative assigned to his hospital, Dr. Hurst has not seen Mr. Kirksey in years. (Ex. D, Hurst Dep. Tr., 68:17-69:7, July 21, 2017.) In addition, Dr. Hurst testified that he stopped using Bard filters around the time the Meridian was on the market, does not know the rates of tilt and caudal migration for the Meridian, and does not know how Meridian® compares clinically to Eclipse or G2X (*Id*. at 102:5-104:14.) Finally, Dr. Hurst does not have any personal knowledge or data regarding what Bard marketing materials other physicians reviewed, or how those materials impacted their decision to implant one filter model over another.

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(Ex. D, Hurst Dep. Tr., 19:14-20, July 21, 2017.) Dr. Hurst also testified that he requested and/or received from plaintiffs' counsel a supplemental list of deposition transcripts and expert reports; however, to the extent those are not included in the Appendix to his Rule 26 Reports, Dr. Hurst testified that he did not review those materials prior to signing and serving his Rule 26 Reports. (Ex. D, Hurst Dep. Tr., 12:1-11, July 21, 2017.) In this case, Bard has produced over 8 million pages of documents, and the parties have conducted dozens of corporate witness depositions. Dr. Hurst has only reviewed but a small fraction of these materials. Not only does Dr. Hurst lack the qualifications to opine on the import of Bard documents related to design, testing, and risk analysis, but he has only reviewed a small portion of the total record evidence in this case, most of which was selected by the lawyers who retained him. Thus, even if he were qualified to comment on these documents, and Bard contends that the is not, he is missing a large part of the evidentiary context here, and simply cannot know what Bard has done or not done in the way of further evaluation, testing, or vetting of its internal data and risk analyses. Courts weigh the lawyer-selected provision of documents to experts heavily against whether the expert's opinions are based upon sufficient facts or data. *See, e.g.*, *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1086-87 (D. Kan. 2002) (excluding an expert's opinion that was based upon preselected documents from counsel because the opinion did "not utilize sufficient facts and data and it is not the product of reliable principles and method"), *aff'd*, 356 F.3d 1326 (10th Cir. 2004); *In re TMI Litig.*, 193 F.3d 613, 698 (3d Cir. 1999) (affirming exclusion of a physician-expert's testimony as unreliable where the physician relied exclusively on documents supplied by plaintiff's counsel in arriving at her opinions).

Courts have excluded or limited the scope of opinions outside an expert's particular area of qualifications. Courts have also excluded expert testimony where such opinions are based on insufficient facts and data chosen by plaintiffs' counsel. Likewise, here, the Court should exclude Dr. Hurst's aforementioned opinions for all of the same reasons.

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3. Dr. Hurst is Not Qualified to Opine That Bard Failed to Communicate to Doctors That the Meridian® Should Be Used Instead of the Eclipse and G2X in Patients Like Ms. Mulkey, Ms. Jones, and Ms. Hyde.

In his Rule 26 Report for bellwether plaintiffs Debra Mulkey, Doris Jones, and Lisa Hyde, Dr. Hurst opines that Bard failed to communicate to doctors that the Meridian should be used instead of the Eclipse (in Ms. Mulkey and Ms. Jones), and the G2X (in Ms. Hyde) (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(iv)*, at 10-11.)

The Bard filters implanted in Ms. Jones and Ms. Hyde pre-dated the time that the Meridian filter went on the market. Ms. Jones filter was implanted on August 24, 2010, (Ex. F, Hurst 6/5/17 Rule 26 Report as to Doris Jones, at 5.) and Ms. Hyde's filter was implanted on February 25, 2011. (Ex. G, Hurst 6/5/17 Rule 26 Report as to Lisa Hyde, at 5.) However, the Meridian filter was cleared by the FDA on August 24, 2011, and was not available on the market until sometime after that date. (Ex. H, August 24, 2011 Letter from FDA to Bard Peripheral Vascular, Inc. re Clearance for Meridian Jugular/Subclavian Delivery Kit) Consequently, Bard could not have offered its Meridian® filter to the implanting doctors in the Jones and Hyde cases, making Dr. Hurst's opinion on this issue inapplicable in those cases.

Ms. Mulkey's filter was placed on April 11, 2012, (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, at 4.) after the date that the Meridian was available; however, Dr. Hurst should not be permitted to argue that the bellwether plaintiffs' treating physicians should have implanted Meridian filters in them, but did not because Bard supposedly failed to notify them that the purportedly "safer" Meridian was on the market at the time those plaintiffs had their Bard filters implanted. Dr. Hurst does not know the specific circumstances behind the treating physicians' choice of filters in their respective patients, what they were aware of or not aware of with respect to the Meridian filter, and how Meridian compares clinically to Eclipse or G2X (Ex. D, Hurst Dep. Tr., 102:5-103:20, July 21, 2017.)

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Based on the record evidence, Dr. Hurst does not know what information Bard shared with the physicians who implanted Bard filters in other patients. He does not know how Bard informed other physicians about new filter models, or the details of any conversations other physicians had with their respective Bard sales representatives. He also does not know the purchasing protocols for other physicians' respective hospitals, how other physicians' hospitals cycle through their filter stock, what considerations other hospitals' purchasing departments make when selecting a device, and whether other physicians have any input on what products their hospitals purchase from manufacturers. Accordingly, Dr. Hurst is speculating when he claims physicians who treated bellwether plaintiffs did not implant the Meridian in patients because Bard failed to communicate to doctors that the Meridian should be used instead of the Eclipse or the G2X.

As demonstrated by the case law cited in Section 1, *supra*, courts have excluded or limited the scope of opinions outside an expert's particular area of qualifications. Likewise, here, the Court should exclude Dr. Hurst's opinions and testimony that Bard failed to communicate to doctors that the Meridian should be used instead of the Eclipse in Ms. Mulkey's case.

CONCLUSION

Because Dr. Hurst is unqualified to opine about the topics identified above, failed to use scientific methodology, and/or simply relied upon limited documents selected by plaintiffs' counsel, his opinions are unreliable, will not help the jury determine the issues, and should be excluded.

DATED this 24th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that August 24th 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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